

**510(k) Summary**

Proprietary Name: VariAx 2 One-Third Tubular Plating System

Common Name: Bone plates

Classification Name and Reference: Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030

Regulatory Class: Class II

Product Codes: 87 HRS: Plate, Fixation, Bone

Sponsor: Stryker Trauma AG  
Bohnackerweg 1  
CH-2545 Selzach  
Switzerland

Contact Person: Estela Celi  
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Date Prepared: May 7, 2014

***Description***

This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the new VariAx 2 One-Third Tubular Plating System. The VariAx 2 One-Third Tubular Plating System is an internal fixation device that consists of straight plates used with compatible screws to fit different types of fractures in the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, small bones in the ankle, fore, mid- and hind foot in adult patients. The subject components will be available sterile and non-sterile. The plates will be available in sizes ranging from 23-191mm in length.

***Intended Use***

The Stryker VariAx 2 One-Third Tubular Plating System is intended for internal fixation of bones in adult patients.

***Indications***

The Stryker VariAx 2 One-Third Tubular Plating System is intended for internal fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, small bones in the ankle, fore, mid- and hind foot in adult patients.

Indications include the following:

- osteotomies and non-unions
- fixation of fractures
- normal bone density and osteopenic bone

***Summary of Technologies***

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following predicate devices:

- K063875 Stryker Foot Plating System
- K011335 Synthes One-Third Tubular Plate

***Non-Clinical Testing***

Non-clinical laboratory testing was performed on the VariAx 2 One-Third Tubular Plating System components to determine substantial equivalence. Testing demonstrated that the VariAx 2 One-Third Tubular Plating System is substantially equivalent to the predicate devices currently cleared for marketing.

The following testing was performed

- 4-Point Bending Out of Plane Testing
- 4-Point Bending Construct Out of Plane Testing

***Clinical Testing***

Clinical testing was not required for this submission.

***Conclusion***

The VariAx 2 One-Third Tubular Plating System is substantially equivalent to the predicate devices identified in this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Stryker Trauma AG  
Ms. Estela Celi  
Senior Regulatory Affairs Specialist  
325 Corporate Drive  
Mahwah, New Jersey 07430

June 20, 2014

Re: K141204  
Trade/Device Name: VariAx 2 One-Third Tubular Plating System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: HRS  
Dated: May 7, 2014  
Received: May 9, 2014

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -A**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K141204

Device Name  
VariAx 2 One-Third Tubular Plating System

### Indications for Use (Describe)

The Stryker VariAx 2 One-Third Tubular Plating System is intended for internal fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, small bones in the ankle, fore, mid- and hind foot in adult patients.

Indications include the following:

- osteotomies, and non-unions
- fixation of fractures
- normal bone density and osteopenic bone

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Elizabeth Frank -S**

Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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